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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,876	11/18/2000	John E. Edwards JR.	259/064	7636

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 10/09/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.



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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

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DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN ONE EXTENDIBLE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to _____ whose telephone number is (703) 30

Office Action Summary

Application No.

09/715,876

Applicant(s)

Edwards Jr. et al.

Examiner

S. Devi, Ph.D.

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 7, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 ~~is~~are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 ~~is~~are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6. 6) ☐ Other:

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DETAILED ACTION

Preliminary Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 08/07/02 (paper no. 10).

Election

- 2) Acknowledgment is made of Applicants' election filed 08/07/02 (paper no. 10) of invention I, claims 1-4, in response to the restriction requirement mailed 05/07/02. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

Status of Claims

- 3) Claims 5-8 have been canceled via the amendment filed 08/07/02.
Claims 1-4 are pending in this application.
Claims 1-4 have been elected and are under examination.

Sequence Listing

- 4) Acknowledgment is made of Applicants' Sequence Listing which has been entered on 04/15/02 (paper no. 4).

Drawings

- 5) The drawings are objected to under 37 C.F.R. 1.84 because of the reasons set forth by the Draftsperson in the attached Form PTO 948 (paper no. 11). Correction is required. Applicants are asked to note the changes effected 03 May 2001, particularly the changes to the 'Timing of Corrections':

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85; 1097 O.G. 36

New formal drawings must be filed with the changes incorporated therein. The art unit number, application number (including series code) and number of drawing sheets should be written on the reverse side of the drawings. Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37 or PTO-37). If delayed, the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" to avoid extension of time fees. Extensions

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of time may be obtained under the provisions of 37 C.F.R. 1.136(a) for filing the corrected drawings (but not for payment of the issue fee). The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTO-37). Within that three month period, two weeks should be allowed for review of the new drawings by the Office. If a correction is determined to be unacceptable by the Office, Applicant must arrange to have an acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time with extension fees. Therefore, applicant should file corrected drawings as soon as possible. Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

Priority

- 6) The instant application claims domestic priority to the provisional application, SN 60/166,663, filed 11/19/199.

Specification - Informalities

- 7) The specification is objected to for the following reasons:
- (a) The instant application at page 4, lines 20 and 21; page 16, line 11; and page 13, lines 18 and 19 recite nucleotide sequences that are longer than 10 nucleotide bases. Neither Figure 7 itself nor the brief description for Figure 7 identify the amino acid sequence depicted in

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Figure 7. However, these sequences are not identified by SEQ ID numbers as required. Applicants should comply with the sequence rules by identifying the sequences with a SEQ ID NO. as required under 37 C.F.R 1.821 through 1.825. APPLICANTS MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R 1.136. In no case may an Applicants extend the period of reply beyond the SIX MONTH statutory period.

(b) The use of the trademark in the instant specification has been noted. For example, see page 14, line 9: "Clontech". The recitation should be capitalized wherever it appears and be accompanied by the generic terminology. Each letter of the trademark must be capitalized. See M.P.E.P 608.01(V) and Appendix 1. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

8) Claims 1-4 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Instant claims broadly read on a protein of any size from any *Candida* species, which Applicants are clearly not in possession of. The breadth of the claims encompasses ASL1 of all *Candida* species and their N-terminal fragments. Applicants disclose the ASL1's amino acid sequence, SEQ ID NO: 8, from a single strain of *Candida albicans*. Claims 1-4 recite insufficient relevant identifying characteristics of the claimed protein obtained from a single species of *Candida*, i.e., a single strain of *Candida albicans*, to allow one skilled in the art to predictably determine complete structures of other ASL1 sequences from other species of *Candida*, or other strains of *Candida albicans*, absent further guidance. The specification on page 4, lines 14-16 only states that similar adhesin molecules "may be obtainable from strains

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belonging to the genera *Candida*". Since the claimed protein genus, cell surface adhesin protein, encompasses an undisclosed number of ASL polypeptides from any species of *Candida*, including *Candida krusei*, *Candida tropicalis* and *Candida parapsilosis* and other strains of *Candida albicans* yet to be discovered, the disclosed structural feature for one ASL1 species (strain) does not constitute adequate description of the claimed broad genus. This is particularly important because ALS1 is described in the art to differ across strains and in some cases, even between ALS1 alleles in the same strain, thus suggesting a strain-dependent variability. See the paragraph bridging left and right columns on page 39 of Hoyer *et al.* (*Mol. Microbiol.* 15: 39-54, January 1995 - Applicants' IDS). ASL1 differed between two strains, for example, strains SB B311 and B792. See last paragraph in right column on page 42 of Hoyer *et al.* Therefore, the disclosure of a single ASL1 sequence from a single strain of *Candida albicans* does not provide an adequate description of the claimed genus of cell surface adhesin protein from any *Candida* strain, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicants were in possession of the genus of cell surface adhesin proteins as claimed. See Written Description Requirement published in *Federal Register*, Vol. 66, No. 4, Friday, 05 January 2001, Notices, p. 1099-1111.

Rejections under 35 U.S.C. § 112, Second Paragraph

- 9) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

- 10) Claims 1-4 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 4 is vague and indefinite in the recitation "derived from" (see line 1), because it is unclear what is encompassed in this limitation. Does the process of "deriving" encompass: extraction, isolation, separation, purification or modification?

(b) Claim 3 is vague in the recitation "encompassing" (see line 1), because it is unclear whether this limitation represents an open claim language equivalent to 'comprising', or a closed claim language being equivalent to 'consisting of'.

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(c) Claim 2 is vague and indefinite in the use of the abbreviated recitation "ALS1" in the claim language. It is suggested that the abbreviation be recited as a full terminology at first occurrence in the base claim, with its abbreviated recitation retained in parentheses.

(d) Claim 1 is vague in lacking the preceding article before in between the recitation "comprising isolated". To obviate the rejection, it is suggested that Applicants replace the recitation with --comprising an isolated--.

Rejection(s) under 35 U.S.C. § 102

11) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12) Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hoyer *et al.* (*J. Bacteriol.* 180: 5334-5343, October 1998) (Hoyer *et al.*, 1998) .

Hoyer *et al.* (1998) teach an isolated N-terminal domain of Als1p protein of *Candida albicans* purified by ammonium sulfate precipitation, centrifugation and dialysis. A composition of the purified N-terminal domain of Als1p protein of *Candida albicans* is taught which is dissolved in PBS (see pages 5336 and 5337).

Claims 1-3 are anticipated by Hoyer *et al.* (1998).

Rejection(s) under 35 U.S.C. § 103

13) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

14) Claims 1-3 are rejected under 35 U.S.C § 103(a) as being unpatentable over Hoyer *et al.* (*Mol. Microbiol.* 15: 39-54, 1995 - Applicants' IDS) (Hoyer *et al.*, 1995).

It is noted that the instant claims do not structurally define the claimed protein either by a molecular weight or by a specific SEQ ID number. The specification identifies an ASL1 protein of a strain of *Candida albicans* as having an amino acid sequence of SEQ ID NO: 8.

The limitation "vaccine" is viewed as the intended use of the claimed product and therefore, is not given any patentable weight.

Hoyer *et al.* (1995) teach the isolation of and an amino acid sequence of an ASL1 protein of *Candida albicans*. See first paragraph in left column on page 50 and Figure 4. A sequence search performed in the Office showed that Hoyer's protein has 100% sequence identity with the amino acid sequence, SEQ ID NO: 8, of the instant application. See the attached search report. Thus, the prior art ASL1 protein is structurally identical to the instantly claimed protein. Hoyer *et al.* (1995) also teach the N-terminus of the ASL1 protein (see Table 1). Although Hoyer *et al.* (1995) do not expressly or positively recite their protein to be an adhesin, Hoyer's protein is viewed as the same as the Applicants' protein. The Office's position that Hoyer's protein is the same as the Applicants' protein is based upon the fact that every characteristic overlapping in Hoyer's and Applicants' disclosure are the same. In spite of the fact that Hoyer *et al.* (1995) fail to expressly recite the adhesion property of their protein, there is sufficient overlap to reasonably conclude that Hoyer's protein is one and the same as the Applicants' protein. Since the prior art protein is structurally the same as the protein recited in the instant claims, it is expected to have the adhesion function. The adhesin limitation recited by the Applicants is inherent to the protein of Hoyer *et al.* (1995). Hoyer *et al.* (1995) also envisioned that ALS1 to be involved in adhesion of the fungal pathogen to host cells (see paragraph bridging left and right columns on page 49).

Hoyer *et al.* (1995) differ from the instant invention in not teaching a pharmaceutical composition comprising their protein.

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However, it routine and conventional in the to produce a pharmaceutical composition of an art-known protein by mixing with an art-known pharmaceutical carrier, such as saline or water. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a pharmaceutical composition using an art-known carrier and Hoyer's protein to produce the instant invention with a reasonable expectation of success. Given the suggested role for the ALS1 protein in the process of adhesion as taught by Hoyer *et al.* (1995), one of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of studying the role of Hoyer's (1995) protein in cell adhesion.

Claims 1-3 are *prima facie* obvious over the prior art of record.

Objection(s)

15) Claims 1 and 4 are objected to for the following reasons:

(a) Claim 1 is objected to for lacking a preceding article before the recitation "comprising isolated and purified cell surface adhesin protein". The objection can be obviated by replacing the recitation with --comprising an isolated and purified cell surface adhesin protein--.

(b) Claim 4 is objected to for including a ",", in between the recitations "*Candida*" and "*parapsilosis*". For clarity, it is suggested that Applicants delete the comma.

Relevant Prior Art

16) The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Hoyer *et al.* (US 5,668,263) and Hoyer *et al.* (US 5,817,466) disclose the ALS1 gene of *Candida albicans* (see entire document).

Remarks

17) Claims 1-4 stand rejected.

18) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a

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week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

19) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October, 2002


S. DEVI, PH.D.
PRIMARY EXAMINER